12-06-07 AF

Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/839,778
Filing Date	April 20, 2001
First Named Inventor	Herron et al.
Group Art Unit	1641
Examiner Name	A. Lam
Attorney Docket Number	0274.02-3278.1US (U-2541.1)

ENCLOSURES *(check all that apply)*

- ☒ Postcard receipt acknowledgment (attached to the front of this transmittal)
- ☒ Duplicate copy of this transmittal sheet in the event that additional filing fees are required under 37 C.F.R. § 1.16
- ☐ Preliminary Amendment
- ☐ Response to Restriction Requirement/Election of Species Requirement dated
- ☐ Amendment in response to office action dated
- ☐ Amendment under 37 C.F.R. § 1.116 in response to final office action dated
- ☐ Additional claims fee - Check No. in the amount of $
- ☐ Letter to Chief Draftsman and copy of FIGS. with changes made in red
- ☐ Transmittal of Formal Drawings
- ☐ Formal Drawings (sheets)
- ☐ Information Disclosure Statement, PTO/SB/08A (08-00); ☐ copy of cited references
- ☐ Supplemental Information Disclosure Statement; PTO/SB/08A (08-00); copy of cited references and Check No. in the amount of $180.00
- ☐ Associate Power of Attorney
- ☐ Petition for Extension of Time and Check No. in the amount of $
- ☐ Petition
- ☒ Reply Brief (7 pages)
- ☐ Certified Copy of Priority Document(s)
- ☐ Assignment Papers *(for an Application)*
- ☐ Terminal Disclaimer
- ☐ Terminal Disclaimer
- ☐ Terminal Disclaimer
- ☐ Other Enclosure(s) *(please identify below)*:

Remarks

The Commissioner is authorized to charge any additional fees required but not submitted with any document or request requiring fee payment under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account 20-1469 during pendency of this application.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Brick G. Power Registration No. 38,581
Signature	
Date	December 5, 2005

CERTIFICATE OF MAILING

Express Mail Label Number: EL994844878US

Date of Deposit: December 5, 2005

Person Making Deposit: Timothy Palfreyman

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Herron et al.

Serial No.: 09/839,778

Filed: April 20, 2001

For: DIAGNOSTIC DEVICE AND METHOD

Confirmation No.: 3373

Examiner: A. Lam

Group Art Unit: 1641

Attorney Docket No.: 0274.02-3278.1US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EL994844878US

Date of Deposit with USPS: December 5, 2005

Person making Deposit: Timothy Palfreyman

REPLY BRIEF

Mail Stop Appeal Brief—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Board of Patent Appeals and Interferences

Sir:

This REPLY BRIEF is being filed in response to the Examiner's Answer of October 5, 2005, in the above-referenced appeal, pursuant to 37 C.F.R. § 41.41, and is being submitted within two months of the mailing date of the Examiner's Answer.

VIII. ARGUMENT

A. REJECTIONS UNDER 35 U.S.C. § 102

1. LEGAL AUTHORITY

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

With respect to inherency, M.P.E.P. § 2112 provides:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . 'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill . . .'' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991).

3. ANALYSIS

"Substantially Simultaneous"

The key issues that were raised in the Examiner's Answer include the meaning of the term "simultaneous," as defined in Jackowski, and the meaning of the phrase "substantially simultaneous," which appears in several of the claims that are pending in the above-referenced application.

As has already been noted in the APPEAL BRIEF in the above-referenced application, Jackowski defines the term "simultaneous" to encompass separate assays for different analytes that are conducted at different points in time, within a given period of time. Jackowski, col. 22, lines 2-19. Jackowski specifically provides that the "given period" of time may be thirty (30) minutes. *See id.* Thus, as long as three different analytes are assayed within thirty (30) minutes of one another, according to Jackowski the assays are conducted "simultaneously."

Jackowski does not provide any express or inherent description of two or more assays being conducted in a manner that one of ordinary skill in the art would consider to be "substantially simultaneous." As one of ordinary skill in the art would readily understand, simultaneous acts occur at the same time. Without limiting the scopes of the claims of the above-referenced application, one of ordinary skill in the art would also readily understand that, although the chemical reactions of different assays may occur at the same time, neither an ordinary human eye and brain nor a single computer processor could evaluate the results of the different assays or determine concentrations of multiple analytes in a sample at exactly the same time. Rather, such evaluation may be effected sequentially, but very close in time to one another (*e.g.*, within a fraction of a second). As sequential evaluations are not perfectly "simultaneous," but could be made very close in time to one another, the term "substantially" has been included in the claims to provide one or ordinary skill in the art with a ready understanding of the scopes and meanings of the claims. *See* M.P.E.P. § 2173.05(b).

To repeat: Jackowksi does not expressly require that assays for two or more analytes be evaluated, the concentrations of analytes be determined, or even that the assays be effected "substantially simultaneously," as that phrase would ordinarily be understood by one of ordinary

skill in the art. Rather, due to its broad definition of the term "simultaneous," compounded by the fact that many of the examples provided thereby include different assay reactions that occur sequentially, Jackowski's disclosure that different assays may be conducted and their results evaluated in a "given period" of time does not amount to an express disclosure that the assays may be evaluated "substantially simultaneously" or that concentrations of multiple analytes in a sample may be determined "substantially simultaneously," as is required of the method recited in independent claim 1.

Furthermore, Jackowski does not include any inherent description that the presence of a plurality of analytes in a sample may be "substantially simultaneously" evaluated or that concentrations of the analytes may be "substantially simultaneously" determined. That is because Jackowski defines "simultaneous" to mean that results from two or more assays may be evaluated several (*e.g.*, thirty (30)) minutes apart from one another. In view of Jackowski's liberal definition of the term "simultaneous," it is apparent that no two assays of any type disclosed therein, even when conducted in the same tube (*see* col. 25, lines 49-51) need to be conducted very closely in time (*i.e.*, within much less than thirty (30) minutes of one another), or "substantially simultaneously," as that phrase would be understood by one of ordinary skill in the art. M.P.E.P. § 2112.

Therefore, Jackowski does not anticipate "substantially simultaneously evaluating the presence of a plurality of analytes in a sample" or "substantially simultaneously determining concentrations of each of the plurality of analytes," which are required elements of the method of independent claim 1.

"Continuing the Determination"

The Examiner has also asserted that Jackowski describes "continuing the substantially simultaneous determination until . . . at least one analyte has been reliably determined to be present in an amount indicative of [a] metabolic or disease state."

In making this assertion, the Examiner has relied upon several statements in Jackowski that either qualitative (presence or absence of analyte) or quantitative (amount of analyte present) results may be obtained by the tests described therein. *See, e.g.,* Examiner's Answer, pages 9 and 10. While it is acknowledged that Jackowski describes both qualitative and quantitative assays, Jackowski does not disclose that anything other than end-point assays, in which a result is evaluated at a specific point in time (*e.g.,* after ten minutes, after thirty minutes of incubation at a specific temperature, etc.), at which point the reaction is assumed to be complete. The Examiner has not pointed to any example or other mention in Jackowski of "continuing" a determination until "at least one analyte has been reliably determined to be present in an amount indicative of [a] metabolic or disease state," as none is present. Therefore, Jackowski does not anticipate this element of the method of independent claim 1.

In view of the foregoing, as well as for the additional reasons that have been set forth in the APPEAL BRIEF, it is respectfully submitted that the subject matter recited in independent claim 1 is allowable over the subject matter described in Jackowski.

Claims 1-6, 8, 9, 11, and 13-21 are each allowable, among other reasons, for depending directly or indirectly from independent claim 1, which is allowable, as well as for the reasons that were set forth in the APPEAL BRIEF.

Explanations as to the further allowability of claims 2 and 8 are provided in the APPEAL BRIEF, and have not been sufficiently rebutted in the Examiner's Answer. Specifically, the Examiner has not demonstrated that Jackowski expressly or inherently discloses that "evaluating the presence of at least one other analyte in [a] sample" may *continue* after a report of a reliable determination that at least one analyte in the sample is present in an amount which is indicative of a metabolic or disease state. Claim 8 is further allowable since Jackowski does not expressly or inherently describe that a substantially simultaneous determination of the presence of at least one analyte in a sample may be effected by reacting at least one analyte in a sample with a corresponding reactive element, the corresponding reactive element being one of a plurality of reactive elements that are arranged in one or more patterns *on the surface of a waveguide.*

B. REJECTIONS UNDER 35 U.S.C. § 103(a)

3. ANALYSIS

The Examiner did not address the apparent lack of motivation to combine teachings from Jackowski and Sawai, as explained in the APPEAL BRIEF.

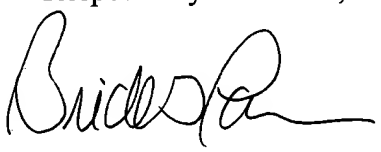
Additionally, Jackowski and Sawai lack any teaching or suggestion that the presence of a plurality of analytes be evaluated substantially simultaneously or that concentrations of each of the analytes be substantially simultaneously determined, it is respectfully submitted that a *prima facie* case of obviousness has not been established.

For these reasons, as well as the other reasons provided in the APPEAL BRIEF, it is respectfully submitted that the subject matter recited in claims 7 and 10-12 is allowable under 35 U.S.C. § 103(a).

XI. CONCLUSION

It is respectfully submitted that each of claims 1-21 is directed to subject matter upon which the rejections of record are based. Accordingly, reversal of the rejections of claims 1-21 is respectfully requested, as is the allowance of each of these claims.

Respectfully submitted,



Brick G. Power
Registration No. 38,581
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: December 5, 2005
BGP/eg
Document in ProLaw